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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,902

11/03/2006

Egil Jellum

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

NOTIFICATION DATE

DELIVERY MODE

09/16/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/549,902	<b>Applicant(s)</b> JELLUM ET AL.	
	<b>Examiner</b> FRANK I. CHOI	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/12/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/2009 has been entered.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn et al. (US Pat. 5,804, 203) in view of US 5,866,168, Denhem et al., Remington's, Hahn (2000), Decaris et al., Lambert et al., Knudsen and Parwaresch et al..

The claimed invention is directed to method of treating inflammation where the inflammation is sub-dermal and in soft tissue by topically administering strontium.

Hahn et al. disclose that skin conditions such as psoriasis produce an intrinsic skin irritation (Column 3, lines 35-50). It is disclosed that strontium is effective in suppressing skin irritation due to sources such as chemical and environmental exposure or tissue inflammation, injury or skin pathology (Column 9, lines 13-25). It is disclosed that the amount strontium can be reduced if a skin penetration-enhancing is added (Column 14, lines 54-68). It is disclosed that the strontium cation is combined with a suitable anion, such as nitrate, chloride, bromide, iodide,

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acetate, amino acids, EDTA, etc. (Column 16, lines 10-38). It is disclosed that the other active ingredients can be added such as anti-acne drugs (Column 19, lines 53-55).

US 5,866,168 disclose that strontium is a substance P antagonist and is effective in the treatment of pain, inflammatory diseases, such as rheumatoid arthritis, psoriasis, acne, etc. (Column 1).

Denhem et al. disclose that radiation therapy cause inflammation of skin tissues (page 132).

Remington's discloses that dimethyl sulfoxide is a permeation enhancer but is also effective as a anti-inflammatory agent (Page 1121).

Hahn (2000) discloses that strontium salts suppress both sensory irritation and inflammation, including neurogenic inflammation (Page 270). It is disclosed that neurogenic inflammation is pathogenically important in many irritating and inflammatory conditions such as irritant and allergic contact dermatitis, psoriasis, atopic dermatitis, astham, rheumatoid arthrtitis, inflammatory bowel disease and other gastrointestinal disorders and that topical application of strontium salts may act to reduce the initial stage of sensory irritation as well as the later stage of frank inflammation (Page 270).

Decaris et al. disclose that substance P is a well known mediator of neurogenic inflammation and plays a role in the development of rheumatoid arthritis and that local inflammation can produce degenerative articular effects from a distance, through systemic or cellular transmission pathways (pages 1951, 1952, 1957, 1958).

Lambert et al. disclose that rheumatoid arthritis is an autoimmune disease characterized by inflammation of the synovial membrane of multiple joints and that substance P has pro-inflammatory properties (Page 269).

Knudsen discloses that mast cells contain potent mediators of inflammation and that stimulation of the mast cell activates the  $\text{Na}^+/\text{K}^+$ -pump which results in release of histamine from the mast cell (Abstract). It is disclosed that pump activity is inhibited by strontium ions (Abstract).

Parwaresch et al. disclose that mast cells are regular constituents of soft tissue and occur with varying frequency in nearly every organ (Abstract).

Hahn et al. disclose the use of strontium to treat inflammation. The difference between Hahn et al. and the claimed invention is that Hahn et al. does not expressly disclose the treatment of inflammation with strontium, the use of dimethylsulphoxide (DMSO) as a permeation enhancer and the treatment of inflammation associated with radiation therapy or arthritis. However, the prior art amply suggests the same as Hahn et al. discloses that strontium is effective in treating irritation where one of the causes of irritation include tissue inflammation; Remington's discloses that DMSO is an anti-inflammatory and permeation enhancer; Denham et al. disclose that radiation therapy can cause inflammation of the skin; US Pat. 5,866,168 discloses that strontium is effective in the treating of inflammatory diseases such a rheumatoid arthritis; Hahn (2000) discloses that strontium salts suppress both sensory irritation and inflammation and that topical application of strontium salts may reduce frank inflammation; Decaris et al. and Lambert et al. disclose that substance P is pro-inflammatory and mediates the development of rheumatoid arthritis; Knudsen discloses that mast cells contain potent mediators of inflammation which release is mediated by the sodium/potassium pump which pump activation is inhibited by strontium ions; and Parwaresch et al. discloses that mast cells are regular constituents of soft tissue and occur in varying frequency in nearly every organ. As such, it would have been well within the skill of and one of ordinary skill in the art would have been

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motivated to modify the prior art as above with the expectation that strontium would be effective in treating various inflammatory conditions including that caused by radiation therapy and rheumatoid arthritis, that DMSO increase the bioavailability of the strontium and provided added anti-inflammatory activity and that strontium would be effective in inhibiting inflammation in sub-dermally and in soft tissues due to its inhibitory effects on the sodium/potassium pump of mast cells thereby inhibiting secretion of histamine from mast cells..

The Examiner has duly considered the Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. The Examiner maintains a flexible schedule, however, the Examiner may generally be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
September 13, 2010

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/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616